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PATENT COOPERATION TREATY

09/936452

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

SLATTERY, John, M
Davies Collison Cave
1 Little Collins Street
Melbourne, Victoria 3000
AUSTRALIE

Date of mailing (day/month/year)	
17 September 2001 (17.09.01)	
Applicant's or agent's file reference 2271868/JMS	**IMPORTANT NOTIFICATION**
International application No. PCT/AU00/00180	**International filing date** (day/month/year) 10 March 2000 (10.03.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
ENTERIX, INC. 348 US Route One Falmouth, ME 04105 United States of America	US	US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [X] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address	State of Nationality	State of Residence
ENTERIX INC. 348 US Route One Falmouth, ME 04105 United States of America	US	US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Mougamadou ABIDINE (Fax 338.87.40)
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Copy for the Elected Office (EO/US) PCT/AU00/00180

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

SLATTERY, John, M
Davies Collison Cave
1 Little Collins Street
Melbourne, Victoria 3000
AUSTRALIE

Date of mailing (day/month/year)
05 September 2001 (05.09.01)

Applicant's or agent's file reference
2271868/JMS

IMPORTANT NOTIFICATION

International application No.
PCT/AU00/00180

International filing date (day/month/year)
10 March 2000 (10.03.00)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
ENTERIX, INC.
857 Princes Point Road
Yarmouth, ME 04096
United States of America

State of Nationality: US
State of Residence: US
Telephone No.: -
Facsimile No.: -
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
ENTERIX, INC.
348 US Route One
Falmouth, ME 04105
United States of America

State of Nationality: US
State of Residence: US
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Mougamadou ABIDINE (Fax 338.87.40)
Telephone No.: (41-22) 338.83.38

NT COOPERATION TREA

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 13 October 2000 (13.10.00)	
International application No. PCT/AU00/00180	**Applicant's or agent's file reference** 2271868/JMS
International filing date (day/month/year) 10 March 2000 (10.03.00)	**Priority date** (day/month/year) 11 March 1999 (11.03.99)
Applicant CHANDLER, Howard, Milne et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

08 September 2000 (08.09.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Manu Berrod
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PCT REQUEST

2271868/JMS

Original (for **SUBMISSION**) - printed on 10.03.2000 10:22:41 AM

0	**For receiving Office use only**	
0-1	International Application No.	
0-2	International Filing Date	
0-3	Name of receiving Office and "PCT International Application"	

0-4	**Form - PCT/RO/101 PCT Request**	
0-4-1	Prepared using	PCT-EASY Version 2.90 (updated 01.01.2000)
0-5	**Petition** The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	Australian Patent Office (RO/AU)
0-7	**Applicant's or agent's file reference**	2271868/JMS
I	**Title of invention**	SAMPLE COLLECTION AND TESTING SYSTEM
II	**Applicant**	
II-1	This person is:	applicant only
II-2	Applicant for	all designated States except US
II-4	Name	ENTERIX, INC.
II-5	Address:	857 Princes Point Road Yarmouth, ME 04096 United States of America
II-6	State of nationality	US
II-7	State of residence	US
II-8	Telephone No.	-
II-9	Facsimile No.	-
II-10	e-mail	-
III-1	**Applicant and/or inventor**	
III-1-1	This person is:	applicant and inventor
III-1-2	Applicant for	US only
III-1-4	Name (LAST, First)	CHANDLER, Howard, Milne
III-1-5	Address:	857 Princes Point Road Yarmouth, ME 04096 United States of America
III-1-6	State of nationality	AU
III-1-7	State of residence	US

PCT REQUEST 2271868/JMS

Original (for **SUBMISSION**) - printed on 10.03.2000 10:22:41 AM

III-2	**Applicant and/or inventor**	
III-2-1	This person is:	applicant and inventor
III-2-2	Applicant for	US only
III-2-4	Name (LAST, First)	LA POINTE, Lawrence, Charles
III-2-5	Address:	67-143 Kurraba Road Neutral Bay, New South Wales 2089 Australia
III-2-6	State of nationality	US
III-2-7	State of residence	AU
IV-1	**Agent or common representative; or address for correspondence** The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	agent
IV-1-1	Name (LAST, First)	SLATTERY, John, M
IV-1-2	Address:	Davies Collison Cave 1 Little Collins Street Melbourne, Victoria 3000 Australia
IV-1-3	Telephone No.	+613 9254 2777
IV-1-4	Facsimile No.	+613 9254 2770
IV-1-5	e-mail	jslattery@davies.com.au
IV-2	**Additional agent(s)**	additional agent(s) with same address as first named agent
IV-2-1	Name(s)	CAINE, Michael, J; HUGHES, E, John, L
V	**Designation of States**	
V-1	Regional Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AP: GH GM KE LS MW SD SL SZ TZ UG ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT EP: AT BE CH&LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE and any other State which is a Contracting State of the European Patent Convention and of the PCT OA: BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT
V-2	National Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	AE AL AM AT AU AZ BA BB BG BR BY CA CH&LI CN CR CU CZ DE DK DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW

PCT REQUEST 2271868/JMS

Original (for **SUBMISSION**) - printed on 10.03.2000 10:22:41 AM

V-5	**Precautionary Designation Statement** In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.		
V-6	**Exclusion(s) from precautionary designations**	NONE	
VI-1	**Priority claim of earlier national application**		
VI-1-1	Filing date	11 March 1999 (11.03.1999)	
VI-1-2	Number	PP9157	
VI-1-3	Country	AU	
VI-2	**Priority document request** The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1	
VII-1	**International Searching Authority Chosen**	Australian Patent Office (ISA/AU)	
VIII	**Check list**	number of sheets	electronic file(s) attached
VIII-1	Request	4	-
VIII-2	Description	18	-
VIII-3	Claims	3	-
VIII-4	Abstract	1	2271868.txt
VIII-5	Drawings	2	-
VIII-7	TOTAL	28	
	Accompanying items	paper document(s) attached	electronic file(s) attached
VIII-8	Fee calculation sheet	✓	-
VIII-16	PCT-EASY diskette	-	diskette
VIII-18	**Figure of the drawings which should accompany the abstract**	-	
VIII-19	**Language of filing of the international application**	English	
IX-1	**Signature of applicant or agent**		
IX-1-1	Name (LAST, First)	SLATTERY, John, M	

FOR RECEIVING OFFICE USE ONLY

10-1	**Date of actual receipt of the purported international application**	
10-2	**Drawings:**	
10-2-1	Received	
10-2-2	Not received	

PCT REQUEST

2271868/JMS

Original (for **SUBMISSION**) - printed on 10.03.2000 10:22:41 AM

10-3	Corrected date of actual receipt due t later but tim ly rec iv d papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/AU
10-6	Transmittal of search copy delayed until search fee is paid	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
SLATTERY, John, M
Davies Collison Cave
1 Little Collins Street
Melbourne, Victoria 3000
AUSTRALIE

TUESDAY, 26 SEP 2000

Date of mailing (day/month/year) 14 September 2000 (14.09.00)	
Applicant's or agent's file reference 2271868/JMS	**IMPORTANT NOTICE**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/AU00/00180	10 March 2000 (10.03.00)	11 March 1999 (11.03.99)

Applicant
ENTERIX, INC. et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   AU,DZ,KP,KR,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,
   GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG,MK,MN,MW,MX,
   NO,NZ,OA,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW
   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   14 September 2000 (14.09.00) under No. WO 00/54024

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, **a demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2271868	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/AU 00/00180**	International filing date *(day/month/year)* 10 March 2000	Priority Date *(day/month/year)* 11 March 1999
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[7] G01N 1/36, 31/22, 33/50, 37/00		
Applicant 1. ENTERIX, INC. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **4** sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand 08 September 2000	Date of completion of the report 09 February 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer M.E. DIXON Telephone No. (02) 6283 2194

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU 00/00180

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of .

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of .

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of .

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of .

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	**10-14**	**YES**
	Claims	**1-9, 15-17**	**NO**
Inventive step (IS)	Claims	**10-14**	**YES**
	Claims	**1-9, 15-17**	**NO**
Industrial applicability (IA)	Claims	**1-17**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

Novelty (N) and Inventive Step (IS) Claims 1-19, 15-17

(a) US 5 869 003
(b) AU 84896/98
(c) AU 61439/96
(d) AU 71410/91
(e) AU 47895/90

(a) US 5 869 003 Claims 1-9, 15-17
Diagrams 1, 2, 4 disclose a diagnostic unit used in the collection and analysis of biological specimen. It comprises a sample collection device in the form of a swab 24 contained in a tubular housing 12. A diagnostic unit 18 containing a test strip 20 is inserted into the bottom of the housing. The top of the housing is capped with a squeeze bulb 30 containing reagents. The features of Claims 1-7, 15 are disclosed. The features of 8, 9 are known in the art. The features of Claims 16, 17 relating to a method for the identification of an analyte of interest in a sample are disclosed in columns 4-7.

(b) AU 84896/98 Claims 1-4
Figure 1 and page 10, line 11 - page 11, line 2 describe a test device for testing the presence of a residue analyte in a sample. A support strip 30 contains a sponge section 32 and a test section 28. The sponge section is used to soak up the specimen fluid which is then allowed to flow to the test section. The whole device is inserted in a housing 12. The features of Claims 1-4 are disclosed by the document.

(c) AU 61349/96 Claims 1-4
Figures 1, 4-6, 9, 10 disclose a test strip 9 contained in an elongated hollow body 2. One end of the strip is immersed in a liquid which then travels up the strip into the test zone by capillary action. The features of Claims 1-4 are disclosed.

(d) AU 71410/91 Claims 1-6
Figure 1 discloses a test unit for use in the collection and analysis of biological specimens. The test unit 10 comprises porous filter members 18, 19 impregnated with one or mere reagents. The specimen is collected by a swab means 22 positioned at the end of a stem 12 which is inserted into a housing 30 to allow the swab means 22 to come into contact with the reagent. The features of Claims 1-6 are disclosed.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of :

(e) AU 47895/90 Claims 1, 3, 5
Figures 2, 3 and page 7, lines 7-28 describe a device for collecting and testing the samples. The combination of cap member 40 and shuttle storage unit 130 serve as a container for testing samples. The sample is injected into the storage combination through the opening 39 by means of a hyperdermic needle. The features of Claims 1, 3, 5 are disclosed.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: Agent :

DAVIES COLLISON CAVE
1 Little Collins Street
MELBOURNE VIC 3000

PCT

NOTIFICATION OF RECEIPT
OF DEMAND BY COMPETENT INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 59.3(e) and 61.1(b), first sentence
and Administrative Instructions, Section 601(a))

Date of mailing *(day/month/year)*	18 SEP 2000 (18/9/00)
Applicant's or agent's file reference: 2271868	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU00/00180	10 MAR 2000 (10/3/00)	11 MAR 1999 (11/3/99)

Applicant: Enterix, Inc. (et al.)

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

8 SEP 2000 (8/9/00)

2. That date of receipt is:

- [X] the actual date of receipt of the demand by this Authority (Rule 61.1(b)).
- [ ] the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(e)).
- [ ] the date on which this Authority has, in response to the Invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3. [ ] **Attention:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the elections(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices)(Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide, Volume II.*

[ ] *(If applicable)* This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/AU **AUSTRALIAN PATENT OFFICE** **PO BOX 200, WODEN ACT 2606, AUSTRALIA** E-mail: pct@ipaustralia.gov.au Facsimile No. 02 6285 3929	Authorized officer JOSEPH BRESIC Telephone No. 02 6283 2357

The demand must be filed directly with the competent International Preliminary Examining Authority. If two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below.

IPEA/_____

PCT

CHAPTER II

DEMAND

Under Article 31 of the Patent Cooperation Treaty:
The Undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION		Applicant's or agent's file reference 2271868/JMS
International application No. PCT/AU00/00180	International filing date (*day/month/year*) (10.03.2000) 10 March, 2000	(Earliest) Priority date (*day/month/year*) (11.03.1999) 11 March, 1999

Title of invention
Sample collection and testing system

Box No. II APPLICANT(S)

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*	Telephone No.:
Enterix Inc. 857 Princes Point Road, Yarmouth, Maine 04096, United States of America	Facsimile No.: Teleprinter No.:

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
United States of America	United States of America

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

CHANDLER, Howard, Milne
857 Princes Point Road
Yarmouth, ME 04096
United States of America

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
Australia	United States of America

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

LA POINTE, Lawrence, Charles
67-143 Kurraba Road
Neutral Bay, 2089
New South Wales, Australia

State *(that is, country)* of nationality:	State *(that is, country)* of residence:
United States of America	Australia

☐ Further applicants are indicated on a continuation sheet.

See Notes to the demand form

International application no.
PCT/AU00/00180

Box No. III AGENT OR COMMON REPRESENTATIVE: OR ADDRESS FOR CORRESPONDENCE

The following person is [X] agent [ ] common representative

and [X] has been appointed earlier and represents the applicant(s) also for international preliminary examination.

[ ] is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

[ ] is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)*

SLATTERY, John, M
CAINE, Michael, J
HUGHES, E, John, L

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Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments:*

1. The applicant wishes the international preliminary examination **to start on the basis of:**

[X] the international application as originally filed

the description [ ] as originally filed
[ ] as amended under Article 34

the claims [ ] as originally filed
[ ] as amended under Article 19 (together with any accompanying statement)
[ ] as amended under Article 34

the drawings [ ] as originally filed
[ ] as amended under Article 34

2. [ ] The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. [ ] The applicant wishes the start of the international preliminary examination **to be postponed** until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69. 1(d)). *This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

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Language for the purposes of international preliminary examination: English

[X] which is the language in which the international application was filed.
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Box No. V ELECTION OF STATES

The applicant hereby **elects all eligible States** ***(that is, all States which have been designated and which are bound by Chapter II of the PCT)***

Excluding the following States which the applicant wishes **not to elect:**

International application no.
PCT/AU00/00180

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

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Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

SLATTERY, John, M
For and on behalf of
the applicant/s

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 00/00180

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5869003	WO	99/53291				
AU	84896/98	WO	99/04267	AU	22097/99	US	5985675
		WO	99/34191				
AU	61349/96	EP	830206	US	5656502	WO	9640434
AU	71410/91	WO	92/10136	EP	515398	US	5078968
		US	5266266	CA	2075193	EP	572637
		US	4978504	US	5238649	WO	93/12421
AU	47895/90	CA	1335787	EP	378353	EP	737443
		JP	3197864	US	4961432	US	5016644
		US	5024237	US	5024238	US	5038793
		US	5077012	US	5301685	US	5358690
		US	5471994	US	5998214	US	4960130
		AU	57678/90	EP	404527	JP	3128461
		US	5003988	US	5133363	AU	61174/90
		AU	63169/94	EP	414513	JP	3170059
		AU	62522/90	EP	419168	JP	3170060
		US	4953561	US	5022411	US	5042502
		US	5137031	US	5139031	AU	63006/90
		CA	2025261	EP	425093	JP	3131760
		US	5224489	AU	80467/91	CA	2046833
		EP	468672	JP	6308126	AU	17789/92
		CA	2084778	EP	533912	WO	92/17110
		AU	17814/92	CA	2085741	EP	535212
		EP	787987	US	5429803	WO	92/18844
		US	5849505	BR	9306818	CH	686324
		EP	654972	WO	94/03103		
DE	19822770	NONE					

END OF ANNEX

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SAMPLE COLLECTION AND TESTING SYSTEM

FIELD OF THE INVENTION

This invention relates to an apparatus and method for the collection and testing of a sample to detect an analyte in the sample, particularly but not exclusively by immunodiagnostic testing. The format of the collection and testing system of the present invention is particularly useful for ascertaining the health status of a human or other animal or a plant or other life form, or the environmental status of a geographical or industrial location by ascertaining the presence or absence of an analyte in a sample. Although useful for immediate sample application and test development, the format is particularly applicable in those circumstances where the sample is collected at one site for test development at another location.

BACKGROUND OF THE INVENTION

A variety of diagnostic devices have been developed for the detection of an analyte of interest in a sample. In those devices in which sample collection and testing functions are non-linked, the transfer of collected sample to testing apparatus introduces a potential source of error. In those devices in which sample collection and testing functions are linked, the devices are dedicated in their entirety to the detection of a particular analyte and are not easily adaptable to a wide range of analyte detection.

With respect to mammalian systems (e.g. humans), samples amenable to analysis using the testing device of the present invention include biological fluids (e.g. blood, urine, semen, saliva, etc.) or excrements. Such biological fluids can carry a variety of analytes, the presence of which can be diagnostic for a particular disease state. The application of the subject invention to the detection of disease states in

humans is of primary importance. However, in addition to use in the context of the diagnosis of serious disease states, the present invention is also useful in a variety of other contexts. Applications in connection with the analysis of microbes, plants, animals, food and water are all anticipated.

For example, ground water samples can be analysed for the presence of contaminants such as atrazine. Food, such as ground beef, can be analysed for the presence of contamination by bacteria such as *E. coli*. In the plant kingdom, the present invention can be applied to the analysis of, for example, pollen, spores and plant vascular fluids. Generally speaking, the only requirement for detection using the device and method of the present invention is that the analyte of interest should be soluble or suspendible in an aqueous solution.

The present invention relates to a device which is useful *inter alia* for the detection of any aqueous soluble or suspendible analyte which is detectable, for example, on the basis of immunological and/or chemical properties. An example of an analyte detected by its immunological properties includes, but is not limited to, an immune interacting molecule such as an antigen, hapten, immunoglobulin or T-cell derived antigen binding molecule. An example of an analyte detected by chemical properties includes an enzyme, catalyst or ligand. Thus, in detection of occult gastrointestinal bleeding as a screen for colo-rectal cancer, using the faecal occult blood (FOB) test, the device of the present invention can be adapted to either guaiac-based testing, or immunological testing. The preferred format for immunological testing is immunochromatography. This format is described generally in U.S. Patent Nos. 5,591,645 and 5,622,871, the disclosures of which are incorporated herein by reference.

Prior to discussing the invention in greater detail, a brief review of the immunochromatography process will be provided to establish certain principles . To detect an analyte of interest by immunochromatography, two binding reagents which

bind specifically and non-competitively to the analyte of interest may be employed. A first specific binding reagent is labelled and is free to migrate. When introduced to a sample to be tested for the presence of the analyte of interest, the first specific binding reagent binds to the analyte of interest, if present. The second specific binding reagent is immobilized in a detection zone on a liquid-conductive solid phase material, the detection zone being remote and downstream from the location of initial contact between the first binding reagent and the analyte of interest. A solvent front carrying the mobile first specific binding reagent complexed with analyte of interest (if present) migrates along the liquid-conductive solid phase material through the detection zone. If analyte is present in the sample, the immobilised second specific binding reagent binds the analyte thereby forming an immobilised sandwich complex comprising the first specific binding reagent (which is labelled), the analyte of interest, and the second specific binding reagent (which is immobilised). Detection of the label immobilised in the detection zone is indicative of the presence of analyte of interest in the sample. In most embodiments, the first and second specific binding reagents are either polyclonal or monoclonal antibodies.

Many diagnostic tests and assays involve the use of samples collected in the field and then either tested immediately, or returned to a central facility for later test development. Such samples may include blood, serum, saliva, milk, faeces, urine or other materials of biological origin, or samples collected from the environment, such as water for analysis for nutrients or contamination.

For example, in the practice of medicine, one or more blood samples may be drawn from a patient in the physician's office and then sent to a pathology laboratory for subsequent testing for one or more analytes. Typically the blood is drawn by venipuncture, using an especially designed needle and blood collection tube (e.g. Vacutainer, Becton Dickinson). The collection of the blood by venipuncture requires trained personnel, the provision of suitable facilities and equipment, refrigerated transport and storage facilities, and finally means for accurate sampling, treatment

(e.g. serum or plasma separation) and dispensing of the blood/plasma/serum into the test or assay equipment. In many cases the blood is only used for one test and, if an effective collection means were available, the blood from a finger prick would be sufficient.

Recently, there has been a marked increase in the use of "Point of Care" (POC) testing, using rapid, self-developing test systems packaged in simple, single-use, disposable test devices. Such POC tests include assays for glucose monitoring, pregnancy and infections such as Streptococcal infection of the throat and Chlamydia infection of the genital tract. Many of these tests, however, introduce a limitation that the test must be conducted immediately at the test site, as the tests have been designed such that the addition of the sample initiates the test. In addition, these tests generally do not incorporate a sample collection system, but rely on the sample being obtained at the time of testing, or else being presented in a separate collection vessel, such as a Vacutainer, as described above.

For many test systems, it is desirable for the sample to be tested to be collected at one site for subsequent test development at another site. In such instances, it is desirable to have a simple, inexpensive and safe means of delivering this testing option, preferably by means of an integral collection and testing system.

Ideally, the prerequisites for such an integrated collection and test system would include:

- generic design, that is, one basic format to suit all test applications;
- simple, accurate and representative sampling, requiring minimal skills and equipment to collect the sample;
- safe, stable, and inexpensive storage of the sample;
- effective reconstitution and/or displacement of the sample to the testing means for development of the test; and

- cost-effective delivery of the test result.

It is an object of the present invention to provide a test format that meets these requirements and is suited for the delivery of samples for either immediate or later testing.

SUMMARY OF THE INVENTION

In one aspect, the present invention provides a device for use in the collection and testing of a sample, comprising:

a. a housing having an internal recess; and

b. a sample collection device;

said housing being adapted to receive said sample collection device in the internal recess therein and to shield a sample collected on said sample collection device, said housing also being adapted to receive an insertable testing element, such that on insertion of said testing element into said housing, the testing element is in liquid-conductive communication with a sample collected on said sample collection device.

In another aspect, the present invention provides a testing device for the identification of an analyte of interest in a sample, comprising:

a. a housing having an internal recess;

b. a sample collection device; and

c. at least one insertable testing element;

said housing being adapted to receive said sample collection device in the internal recess therein and to shield a sample collected on said sample collection device, said housing also being adapted to receive the or each said insertable testing element such that, on insertion of said testing element into said housing, the testing element is in liquid-conductive communication with a sample collected on said sample collection device.

In another aspect, the present invention provides a method for the identification of an analyte of interest in a sample by use of a testing device as broadly described above, comprising:

a. collecting a sample on the sample collection device,

b. inserting said sample collection device into the internal recess of the housing of the testing device,

c. inserting the insertable testing element into the housing such that the testing element is in liquid-conductive communication with said sample, and optionally

d. applying a solvent to said sample to enable transfer of at least part of said sample, or a component thereof, to the testing element.

Throughout this specification, unless the context requires otherwise, the word "comprise", and or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

DETAILED DESCRIPTION OF THE INVENTION

An important feature of the testing device of the present invention is that the single device serves a collection and testing function. However, the testing function is not linked to collection of a sample. That is, the collection of a sample (e.g. by a patient in the home) and application to the testing device does not yield a test result. In order to determine the test result, an insertable testing element must be inserted into the device, and if the sample has previously been dried or desiccated the sample must be rehydrated.

Preferably, the sample is a liquid containing sample. The sample may itself be a liquid or it may be in a particulate or solid form which is then hydrated prior to testing. In a preferred but not essential aspect of this invention, the testing device is adapted so that a sample applied to the sample collection device (for example, by a patient in

the home) may be dried or desiccated on the sample collection device within the housing of the testing device.

In accordance with this invention, the testing element is adapted to be inserted into the housing of the device so that the testing element is in liquid-conductive communication with the sample collection device as described above.

Preferably, the housing is provided with a first window or aperture communicating with the internal recess within the housing for insertion of the sample collection device, together with at least one additional window or aperture which is separate from the first window or aperture and which also communicates with the internal recess for insertion of the, or each, insertable testing element so that the testing element is in liquid-conductive communication with a sample collected on said sample collection device.

As used herein, the term "liquid-conductive communication" shall be taken to mean that a solvent applied to a sample is capable of being in liquid-conductive communication with the testing element under sufficient conditions of hydration to enable transfer of at least part of said sample, or a component thereof, to the testing element.

The three components of a preferred embodiment of the testing device of the present invention are:

1. a sample collection device designed to collect, and store, a predetermined (that is a quantified or semi-quantified) amount of sample,
2. a housing having an internal recess designed to accept and protect the sample collection device and, if required, offer sufficient ventilation to allow dehydration of a liquid sample collected on the sample collection device, and

3. a testing element designed so that, on insertion into the housing, liquid-conductive contact is established with the sample collection device.

Each of the components is designed, or selected, for its suitability for inexpensive, high-speed, automated manufacture by established manufacturing technologies.

The sample collection device is designed to enable sample collection without the requirement for laboratory facilities, equipment, or highly trained or skilled personnel. For some applications, the collection device may be an existing device, such as a swab. Other applications will require a custom designed device to accurately meter, accept and store a predetermined amount of specimen. In many cases, this component will consist of a hydrophilic, porous matrix, of defined volumetric capacity, affixed to the base of a dipstick or handle, so that collection of a sample involves touching the matrix to the sample, thus filling the matrix with a measured volume of the sample. The preferred embodiment of the sample collection device described herein is designed for manufacture by established high-speed laminating and die-cutting processes.

The housing is also designed for manufacture by rapid packaging technologies, such as "Form, Fill and Seal" technology. The housing has an internal recess which serves to store and protect the sample, as well as facilitate the transfer of the sample to the testing element at the time of test initiation. It may also house or receive any reagents necessary for initiation or completion of the test procedure.

In many instances, the testing element will be an immunochromatographic test strip, such as are used in numerous existing POC tests. Most of the existing tests, however, have the test strip mounted in a housing so that the addition of the sample initiates the development of the test. These tests are therefore not suitable for remote sampling and centralised test development. In addition, the existing POC tests are

expensive to manufacture. The test strip and housing components must be assembled and then stored dry, as the reagents in the test strip are subject to rapid degradation in the presence of humidity. Desiccated packaging of significant cost and volume must therefore be provided. In accordance with the present invention, the test strip is inserted into the housing at the time of testing, thus avoiding any assembly costs. These test strips may also be stored in bulk, for example in a desiccated container, thus saving on packaging and storage costs.

In another embodiment of the present invention, the testing device may comprise two or more insertable testing elements each of which, when inserted, is in liquid-conductive communication with the sample collection device. In this embodiment, the testing elements may be either the same or they may be different. In the former case, replicate tests may be carried out on the sample applied to the sample collection device. In the latter case, different tests may be carried out on the same sample applied to the sample application matrix. By way of example, in FOB testing for screening for colo-rectal cancer, one insertable testing element may be a guaiac-based test strip, whilst another insertable testing element may be an immunochromatographic test strip.

Given the description which follows, one of skill in the art will recognize that the testing element or elements may be provided in an array of alternative embodiments. Referring to the immunochromatographic embodiment, for example, a required element of the test strip is a liquid-conductive solid phase material to which a detection reagent (described above in the brief review of immunochromatography as the second specific binding reagent) may be immobilized. This solid phase material is preferably nitrocellulose. Nitrocellulose is a charged matrix to which an appropriately charged reagent, such as a monoclonal antibody, may be immobilized without prior chemical treatment. Alternatives such as filter paper may also be used, however, chemical coupling (e.g., CNBr coupling) is required to attach a charged reagent such as an antibody to a matrix of this type.

A preferred liquid-conductive solid phase material is a nitrocellulose membrane having a pore size of at least about 1 micron. Nitrocellulose membranes best adapted for use in connection for immunochromatography of this type have a pore size of about 5-20 microns. The selection of particular pore size dictates flow rate. Depending upon the particular application, a faster or slower flow rate may be indicated and an appropriate solid phase material is selected.

To facilitate handling, it is desirable to provide a backing to the nitrocellulose membrane. A thin plastic sheet stock (e.g., lexan or polystyrene) may be cut to provide a suitable water resistant backing for the solid support. Such sheet stock is selected so as not to interfere with the reading of a test result. For example, the selection of a white or clear sheet stock is generally preferred. In an alternative embodiment, the liquid conductive solid phase material may be sandwiched between such water resistant sheet stock.

When inserted into the housing, the or each testing element is designed to be in liquid-conductive communication with the sample collection device. Preferably, this liquid-conductive communication is direct, for example between the sample collection device and the liquid-conductive solid phase material of an immunochromatographic or other testing element. In a preferred immunochromatography embodiment, additional liquid-conductive elements may be incorporated in or on the testing element. For example, a conjugate pad may be provided which, in use, is disposed between the sample collection device and the liquid-conductive solid phase material of the testing element. As will be discussed in greater detail below, the conjugate pad provides a matrix for the deposition of a labelled detection reagent which is free to migrate when rehydrated (the first specific binding reagent in the brief review of immunochromatography provided above). The sample may be dehydrated or desiccated within the sample collection device prior to the insertion of the testing element. At the time of rehydration during the testing step, the labelled detection reagent within the conjugate pad is also resuspended and resolubilised. If analyte is

present in the sample, the labelled reagent binds to the analyte and the complex is carried along with the solvent front to the detection zone of the testing element.

At the end of the testing element distal to the conjugate pad when in use, an optional absorbent pad is attached, in communication with the liquid-conductive solid phase material. This pad provides a solvent sink which drives the migration of the liquid sample through the detection zone. It is important that the absorbent pad have sufficient volume to drive the migration to the extent that substantially all unbound labelled detection reagent is carried beyond the detection zone of the testing element. One of skill in the art will recognize that an absorbent pad is a non-essential element. The need for this element can be obviated, for example, by extending the length of the liquid-conductive solid phase material beyond the detection zone such that a sufficient volume is carried through the detection zone.

In use, a sample is collected on the sample collection device in a conventional manner. For example, in FOB testing, a faecal smear may be collected on the sample collection device, or alternatively, toilet bowl water may be sampled using an absorbent swab. In the latter sampling method, a short time may be allowed for haemoglobin to diffuse from the stool prior to sampling, or the swab may be used as the sample collection device to disperse the stool into the toilet bowl water. The swab is then used to sample the water.

Depending upon the nature of the analyte, the testing device with sample collection device inserted into the internal recess of the housing of the device may be stored in this form for a period of days, weeks or months prior to testing. To determine the presence of an analyte, the sample is rehydrated by adding an appropriate solvent to the sample collection device. The solvent may be added through a solvent application aperture in the housing which is in communication with the sample collection device. Preferably, solvent applied through such a solvent application aperture should migrate through the region of the sample collection device where

sample was actually applied, prior to reaching the point on the sample collection device which is in liquid-conductive communication with the testing element.

The labelled detection reagent may be introduced into the immunochromatography assay in a variety of ways. For example, the labelled detection reagent may be solubilized in the solvent used to rehydrate the contents of the sample collection device prior to the resolubilisation of the sample or its components. Alternatively, as discussed above, the labelled detection reagent may be introduced in solution into the conjugate pad and desiccated *in situ*. In this embodiment, the labelled detection reagent is resolubilized as the resolubilization solvent migrates from the sample collection device to the testing element. In yet another embodiment, a solution containing the labelled detection reagent may be added to the sample collection device prior to the application of the sample. This solution is then desiccated *in situ*. In this embodiment, analyte of interest, if present, and labelled detection reagent will be solubilized from the dry sample collection device at the time of testing.

Of the embodiments described in the preceding paragraph, the use of a conjugate pad is preferred for most embodiments. The addition of the labelled detection reagent to the resolubilization solvent prior to sample resolubilization has the disadvantage of using the expensive detection reagent (which could require storage at 4°C) in an inefficient manner. With respect to the desiccation *in situ* of the labelled detection reagent in the sample collection device prior to sample collection, this would result in the establishment of a testing device in which the sample collection device is dedicated to a particular assay. One of the many benefits of the disclosed device is the fact that the housing (together with other elements of the device excluding the testing element) is totally generic. Thus, the housing of the testing device as well as the sample collection device can be purchased in bulk and stored as needed for any of a variety of testing requirements. The relatively expensive test-specific component is

the testing element which can be selected for a particular need and used in conjunction with the generic housing and sample collection device.

Preferably the labelled detection reagent is a monoclonal or polyclonal antibody specific for a first epitope of the analyte of interest, coupled to a detectable label. The detectable label can be coupled to the antibody by any of the applicable techniques known in the art including, for example, covalent bonding and passive adsorption.

The detectable label may be a direct or an indirect label. A direct label is a label which is readily visible in its natural state, either to the naked eye, or with the aid of optical devices. A label which is visible only in the presence of external stimulation , such as ultraviolet light, is also considered to be a direct label. Examples of direct labels include dye sols (e.g., colloidal carbon), metallic sols (e.g., gold and iron), fluorescent particles and coloured latex particles.

Indirect labels require the addition of one or more developing reagents, such as substrates, to facilitate detection. Such labels include, for example, enzymes such as alkaline phosphatase and horseradish peroxidase.

The immobilized capture reagent is also typically a monoclonal or polyclonal antibody which is specific for a second epitope or range of epitopes on the analyte of interest. Thus, analyte present in the sample, whether bound by the detection reagent or not, is bound by the immobilized binding reagent in the detection zone. In a case in which a direct label is employed, a visible line appears on the liquid-conductive solid support as bound label accumulates in the detection zone. The appearance of this line may be diagnostic for the presence of analyte of interest in the sample.

An optional control zone can also be integrated into the testing element. The function of a control zone is to convey an unrelated signal to the user which indicates only that the testing process is complete and that the binding interaction which results

in the detectable unrelated signal has taken place as expected. For example, the control zone may comprise an "anti-mouse" polyclonal antibody immobilized to the liquid-conductive solid phase material, preferably downstream of the detection zone. Assuming that the detection reagent is a murine monoclonal antibody linked to a detectable label, detection reagents not bound in the detection zone through a sandwich interaction involving the analyte of interest will ultimately bind in the control zone. In the absence of a signal in the detection zone, a control zone signal would indicate to the user that, for example, the sample contained nothing that resulted in general interference with an immunological assay. It can be imagined, for example, that extremes of pH or salt concentration could result in general interference through conformational changes or physical destruction on one or more of the participants in the immunologically based interaction to be detected. The inclusion of a control zone functions to provide a degree of confidence with respect to such variables.

The analyte of interest is determined in advance to be one which is diagnostic of a particular condition. For example, in connection with FOB tests, the analyte of interest is preferably human hemoglobin. Other examples of analytes of interest are described below.

The method and apparatus of the present invention is applicable to detecting analytes in humans and other animals. Other animals include primates, livestock animals (e.g. cows, sheep, horses, donkeys, pigs), laboratory test animals (e.g. rabbits, mice, rats, guinea pigs, hamster), companion animals (e.g. dogs, cats) and captive wild animals. The present invention also extends to detecting analytes in plants (e.g. monocotyledons and dicotyledons) and other life forms (e.g. microbes, yeasts, fungi, moulds). The present invention may also be used to detect analytes in geographic and industrial locations, including soil, oceans, rivers, water storage regions, toxic waste dumps, building sites, mining areas (e.g. coal, bauxite, uranium, graphite amongst many others) as well as in the air. The health status of humans, and other animals or plants or other life forms may be deduced or determined in the

presence or level of analyte or by the absence of analyte. The environmental status may also be ascertained such as determining the presence of contaminants in various geographic or industrial locations.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates a testing device in accordance with the present invention which is particularly adapted for use with samples or specimens collected on an absorbent swab.

Figure 2 illustrates an immunochromatographic test step for use in the testing device of the present invention.

Figure 3 illustrates an alternative sample collection device for use in the testing device of the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Figure 1 illustrates the testing device of the present invention in a format which uses a swab as the sample collection device. A swab may be used as a general sampling device for many liquid or moist specimen types, provided that they do not require an accurately measured volume of sample. Swabs are frequently used for obtaining infectious clinical samples, for example for testing for *Streptococcus pyogenes* Type A (Strep.A) in cases of throat infection.

The current POC tests for Strep.A use a swab to collect a sample or specimen from the region of the throat suspected of being infected. Reagents are added to the head of the swab to form nitrous acid, typically sodium nitrite solution and a weak acid such as acetic acid. Nitrous acid acts on the Strep.A bacteria to release its diagnostically specific antigen. This extraction of antigen may be "off board", for

example in a reaction cup provided with the test, or "onboard", with the swab inserted into a receptacle in the housing of the test. Typically, an extraction time of 1 minute is allowed for release of antigen before commencement of the test.

Figure 1(a) is an exploded drawing showing the general construction of the housing of the testing device of this embodiment of the invention, while

Figure 1(b) shows the assembled housing.

In this embodiment, the housing comprises a base (11) which is preferably made of a plastic that may be vacuum or pressure formed to provide a recess or cavity (12), as illustrated. A cover (13), preferably made of plastic or other waterproof material and provided with two openings (14) and (15) is sealed to the base (11), but not the recess (12), by adhesive or other sealing or aperture means. A plastic cover strip (16) is sealed to the cover (13), as illustrated so that the aperture (15) is covered, but with the strip remaining open along one edge (17). The shaded areas (18) on the cover strip (16) represent the sealing or glue pattern.

Figure 1(c) shows the assembled housing with a swab (19) inserted in the recess (12) and immunodiagnostic test strip (20) inserted under the plastic cover strip (16).

Figure 2 illustrates the generalised construction of an immunodiagnostic test strip suitable for use with this testing device.

When the swab (10) is fully inserted into the recess (12) in the housing via the aperture (14), its head (which contains the sample or specimen) is exposed in the other aperture (15). The addition of extraction reagents to the recess, for example via aperture (14), enables reagent to accumulate in the head of the swab, thereby releasing any Strep.A antigen that may be present. After allowing time for this

extraction, the test strip (20) is inserted under the cover strip (16) so that it makes liquid-conductive contact with the head of the swab at the origin of the test strip. Liquid migrates from the swab to the test strip, thereby developing the test result in the test strip.

In a further development of this embodiment of the testing device, the extraction reagents, or other reagents required in other test formats, may be blister packed within the housing so that the insertion of the swab bursts the blister packaging to the reagents.

In addition, some tests for pathogens (e.g. Strep.B, some pathogenic *E. coli*) require a period of culture to increase the concentration of the organism before testing. In this format, liquid culture medium may be added (or issued pre-packed) to the housing prior to insertion of the swab or other sample collection device in order to allow "onboard" culturing.

For specimens that require a specified volume of reagent, e.g. for semi-quantitative or quantitative assays, a specifically designed sample collection device may be used instead of a swab as described above. It is anticipated that the same generic housing illustrated above would be used with such a semi-quantitative or quantitative sample collection device.

A preferred embodiment of such a collection device is illustrated in Figure 3, and comprises a plastic handle (21), (e.g. of polystyrene or similar plastic) which has laminated thereto a hydrophilic matrix of defined absorptive volume (22). Suitable matrix materials include porous plastic, paper, non-woven synthetic fabrics, fibreglass, etc. Porous plastics made by Porex (Fairburn, GA, USA) of high molecular weight polyethylene have been found to be particularly suitable. This collection device has the advantage that it may be manufactured inexpensively by established industrial web-handling, laminating and die-cutting processes.

In use, the matrix of the collection device is touched to the liquid to be sampled until it has absorbed its predetermined fill volume of sample. The collection device is then inserted into the recess in the housing and the test completed by insertion of the immunodiagnostic test strip as described above.

Persons skilled in the art will recognise that many modifications or variations may be made to the devices described in detail herein in order to suit other testing purposes or by way of adaptation for optimal function, without departing from the spirit and scope of the present invention as broadly described above.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A device for use in the collection and testing of a sample, comprising:
   a. a housing having an internal recess; and
   b. a sample collection device;
   said housing being adapted to receive said sample collection device in the internal recess therein and to shield a sample collected on said sample collection device, said housing also being adapted to receive an insertable testing element such that, on insertion of said testing element into said housing, the testing element is in liquid-conductive communication with a sample collected on said sample collection device.

2. A testing device for the identification of an analyte of interest in a sample, comprising:
   a. a housing having an internal recess;
   b. a sample collection device; and
   c. at least one insertable testing element;
   said housing being adapted to receive said sample collection device in the internal recess therein and to shield a sample collected on said sample collection device, said housing also being adapted to receive the or each said insertable testing element such that, on insertion of said testing element into said housing, the testing element is in liquid-conductive communication with a sample collected on said sample collection device.

3. A device according to claim 1 or claim 2, wherein, on insertion of the testing element into the housing, the testing element is in direct liquid-conductive communication with a sample collected on the sample collection device.

4. A device according to claim 1 or claim 2, wherein the sample collection device is a swab.

5. A device according to claim 1 or claim 2, wherein the sample collection device collects a predetermined amount of the sample.

6. A device according to claim 5, wherein the sample collection device comprises a hydrophilic, porous matrix of defined volumetric capacity, affixed to the base of a dipstick or handle.

7. A device according to claim 1 or claim 2, wherein the housing is provided with a first window or aperture communicating with the internal recess within the housing for insertion of the sample collection device, together with a least one additional window or aperture which is separate from the first window or aperture and which also communicates with the internal recess for insertion of the, or each, insertable testing element so that the testing element is in liquid-conductive communication with a sample collected on said sample collection device.

8. A device according to claim 2, wherein the insertable testing element is a guaiac-based test strip.

9. A device according to claim 2, wherein the insertable testing element is an immunochromatographic test strip.

10. A device according to claim 2, which comprises two or more insertable testing elements each of which, when inserted into the housing, is in liquid-conductive communication with a sample collected on the sample collection device.

11. A device according to claim 10, wherein the testing elements are the same elements.

12. A device according to claim 10, wherein the testing elements are different elements.

13. A device according to claim 10, wherein at least one of said testing elements is an immunochromatographic test strip.

14. A device according to claim 10, wherein at least one of said testing elements is a guaiac-based test strip.

15. A device according to claim 1 or claim 2, wherein the housing is provided with a solvent application aperture in communication with the internal recess.

16. A method for the identification of an analyte of interest in a sample, using a device according to claim 1 or claim 2 comprising:
    a. collecting a sample on the sample collection device,
    b. inserting said sample collection device into the internal recess of the housing of the device, and
    c. inserting the insertable testing element into the housing such that the testing element is in liquid-conductive communication with said sample.

17. A method according to claim 16, further comprising:
    d. applying a solvent to said sample to enable transfer of at least part of said sample, or a component thereof, to the testing element.

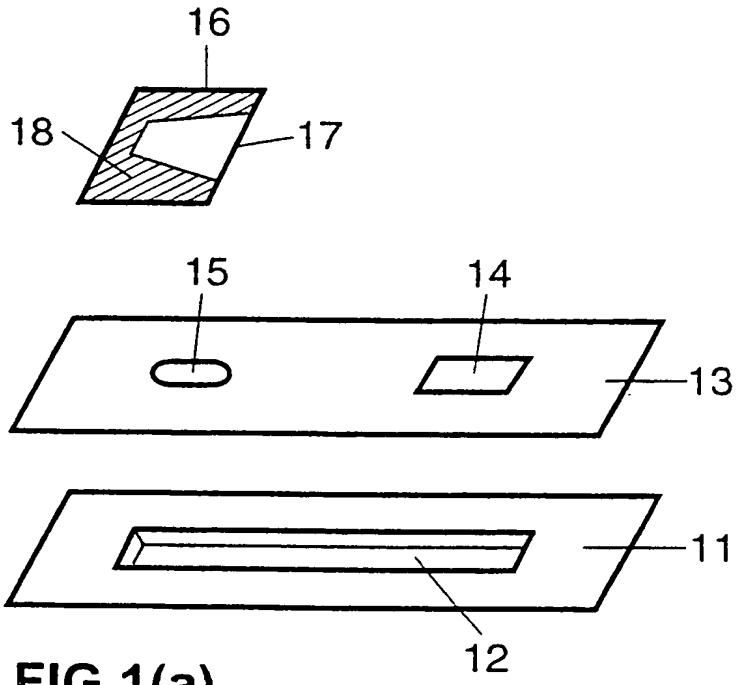
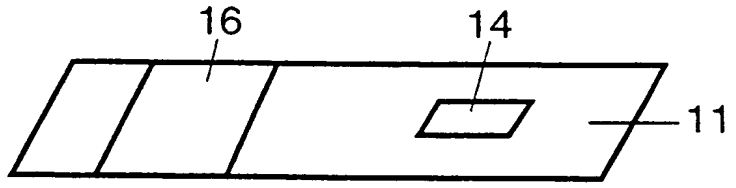


FIG 1(a)

FIG 1(b)



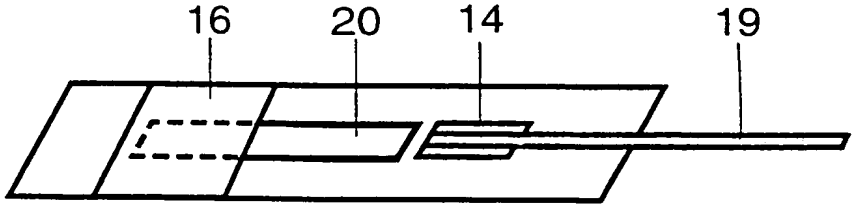


FIG 1(c)

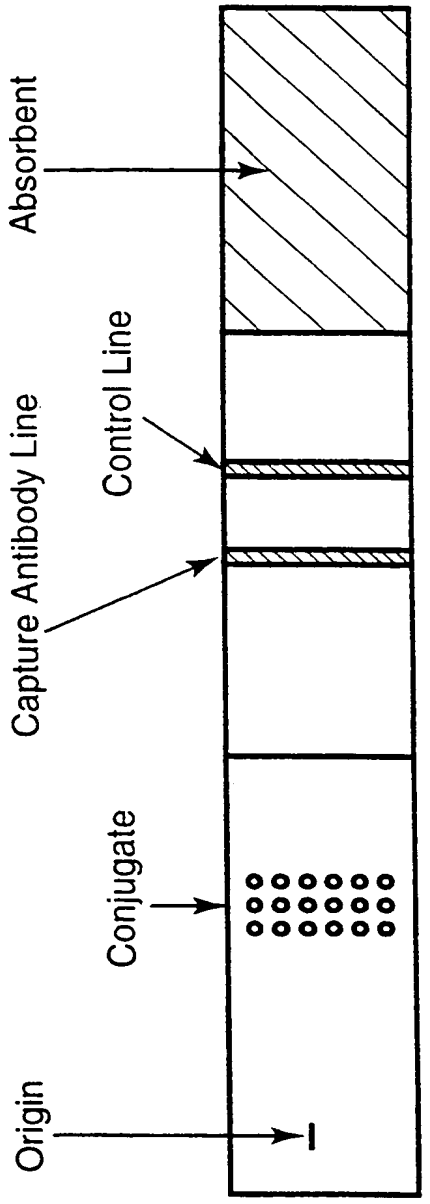

Absorbent
Control Line
Capture Antibody Line
Conjugate
Origin

FIG 2

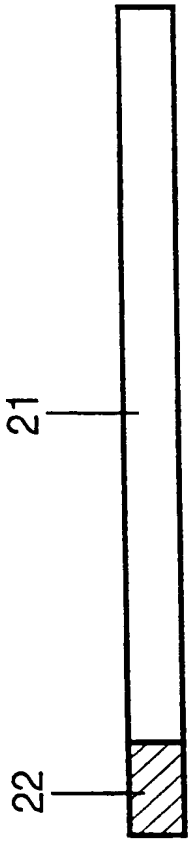

21
22

FIG 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/00180

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[7]: G01N 1/36, 31/22, 33/50, 37/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC G01N 1/36, 31/22, 33/50, 37/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU : IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI and Japio

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5869003 A (NASON) 9 February 1999 Col 4, line 1 - col 7, line 22; figs 1-3	1-9, 15-17
X	AU 84896/98 A (CHARM SCIENCES, INC.) 10 February 1999 Page 10, line 11 - page 11, line 2; fig 1	1-4
X	AU 61349/96 A (DIAGNOSTIC CHEMICALS LIMITED) 30 December 1996 Figs 1, 4-6, 9, 10	1-4

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 April 2000	- 3 MAY 2000

Name and mailing address of the ISA/AU	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/00180

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AU 71410/91 A (NASON) 8 July 1992 Fig 1	1-6
X	AU 47895/90 A (CANCER DIAGNOSTICS, INC.) 19 July 1990 Page 7, lines 17-28; figs 2, 3	1, 3, 5
A	DE 19822770 A (LRE Technology Partner GmbH) 25 November 1999	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 00/00180

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5869003	WO	99/53291				
AU	84896/98	WO	99/04267	AU	22097/99	US	5985675
		WO	99/34191				
AU	61349/96	EP	830206	US	5656502	WO	9640434
AU	71410/91	WO	92/10136	EP	515398	US	5078968
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		US	4978504	US	5238649	WO	93/12421
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		JP	3197864	US	4961432	US	5016644
		US	5024237	US	5024238	US	5038793
		US	5077012	US	5301685	US	5358690
		US	5471994	US	5998214	US	4960130
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		US	5003988	US	5133363	AU	61174/90
		AU	63169/94	EP	414513	JP	3170059
		AU	62522/90	EP	419168	JP	3170060
		US	4953561	US	5022411	US	5042502
		US	5137031	US	5139031	AU	63006/90
		CA	2025261	EP	425093	JP	3131760
		US	5224489	AU	80467/91	CA	2046833
		EP	468672	JP	6308126	AU	17789/92
		CA	2084778	EP	533912	WO	92/17110
		AU	17814/92	CA	2085741	EP	535212
		EP	787987	US	5429803	WO	92/18844
		US	5849505	BR	9306818	CH	686324
		EP	654972	WO	94/03103		
DE	19822770	NONE					

END OF ANNEX

PCT

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International Bureau

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(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: SAMPLE COLLECTION AND TESTING SYSTEM

(57) Abstract

A testing device for the identification of an analyte of interest in a sample, comprises a housing having an internal recess (14); a sample collection device (19) and at least one insertable testing element (20); the housing being adapted to receive the sample collection device in the internal recess therein and to shield a sample collected on the sample collection device, the housing also being adapted to receive the or each insertable testing element such that, on insertion of the testing element into the housing, the testing element is in liquid conductive communication with a sample collected on the sample collection device.